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Kuypers

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(54) **CORD COLLECTION CLAMP**

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This patent is subject to a terminal disclaimer.

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(51) **Int. Cl.**

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A61B 17/3211	(2006.01)
A61B 10/02	(2006.01)
A61M 1/02	(2006.01)
A61B 17/32	(2006.01)
A61B 17/3209	(2006.01)

(Continued)

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(58) **Field of Classification Search**

CPC A61B 17/122; A61B 5/1405; A61B 10/02; A61B 17/3211; A61B 2017/1225; A61B 2017/320064; A61M 1/0019; A61M 1/02

See application file for complete search history.

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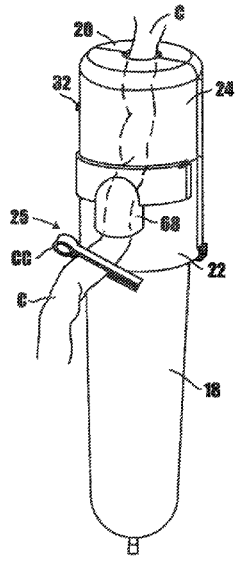
(57) **ABSTRACT**

The present disclosure provides an apparatus, and methods of using same, for collecting blood from an umbilical cord in a sterile environment that includes an umbilical cord retaining assembly and a blood collection assembly rotatably connected to the umbilical cord retaining assembly. A cord cutting blade, which is carried by the blood collection assembly, functions to cut the umbilical cord when the blood collection assembly is rotated relative to the umbilical cord retaining assembly. After the umbilical cord is cut, blood flows by force of gravity into the blood collection region of the blood collection assembly to which a blood collection bag can be interconnected.

10 Claims, 8 Drawing Sheets



(51) **Int. Cl.**
A61B 5/15 (2006.01)
A61B 17/42 (2006.01)

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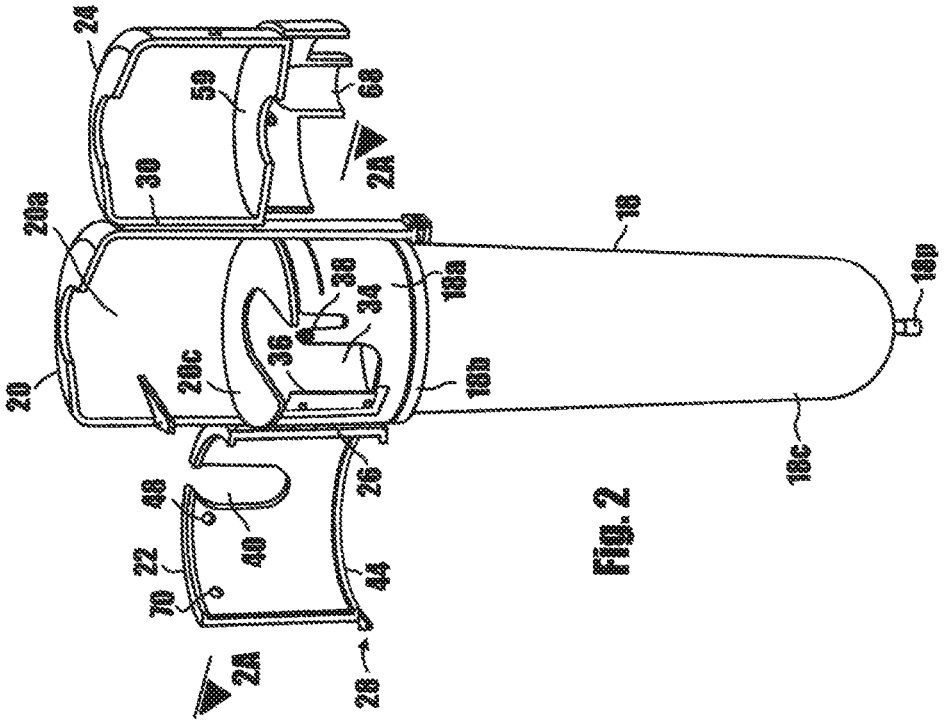
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30
20a
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38
18a
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18d
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2A

Fig. 2

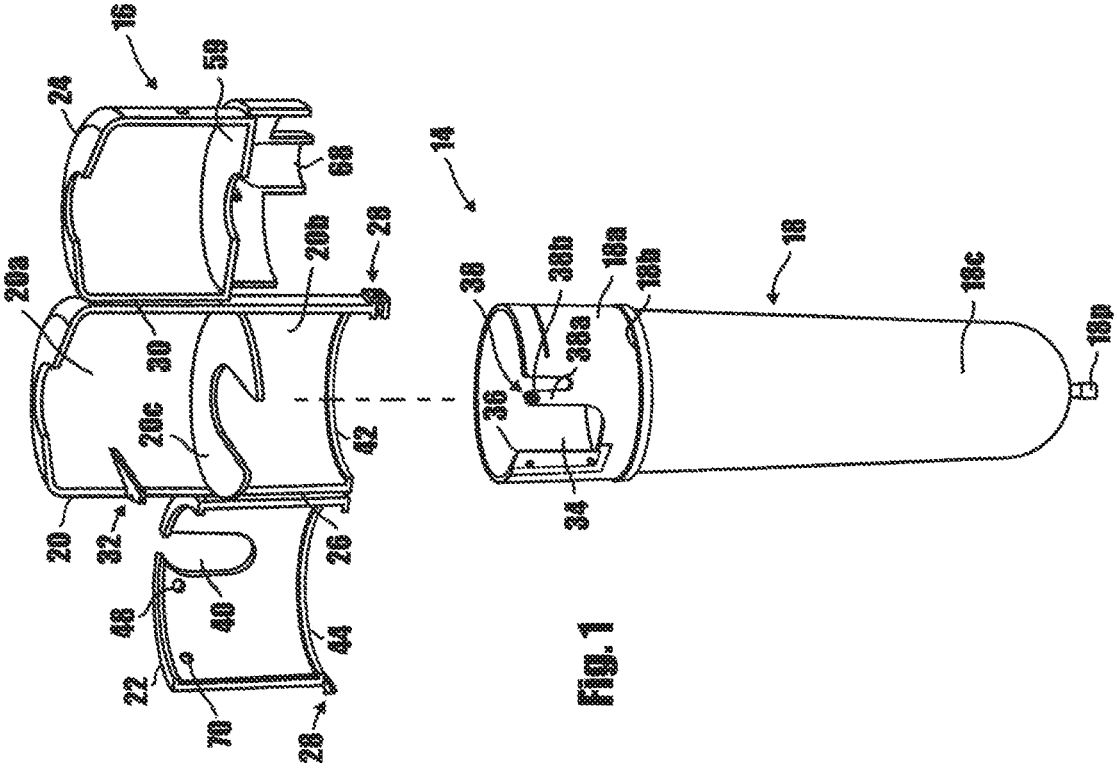
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Fig. 1

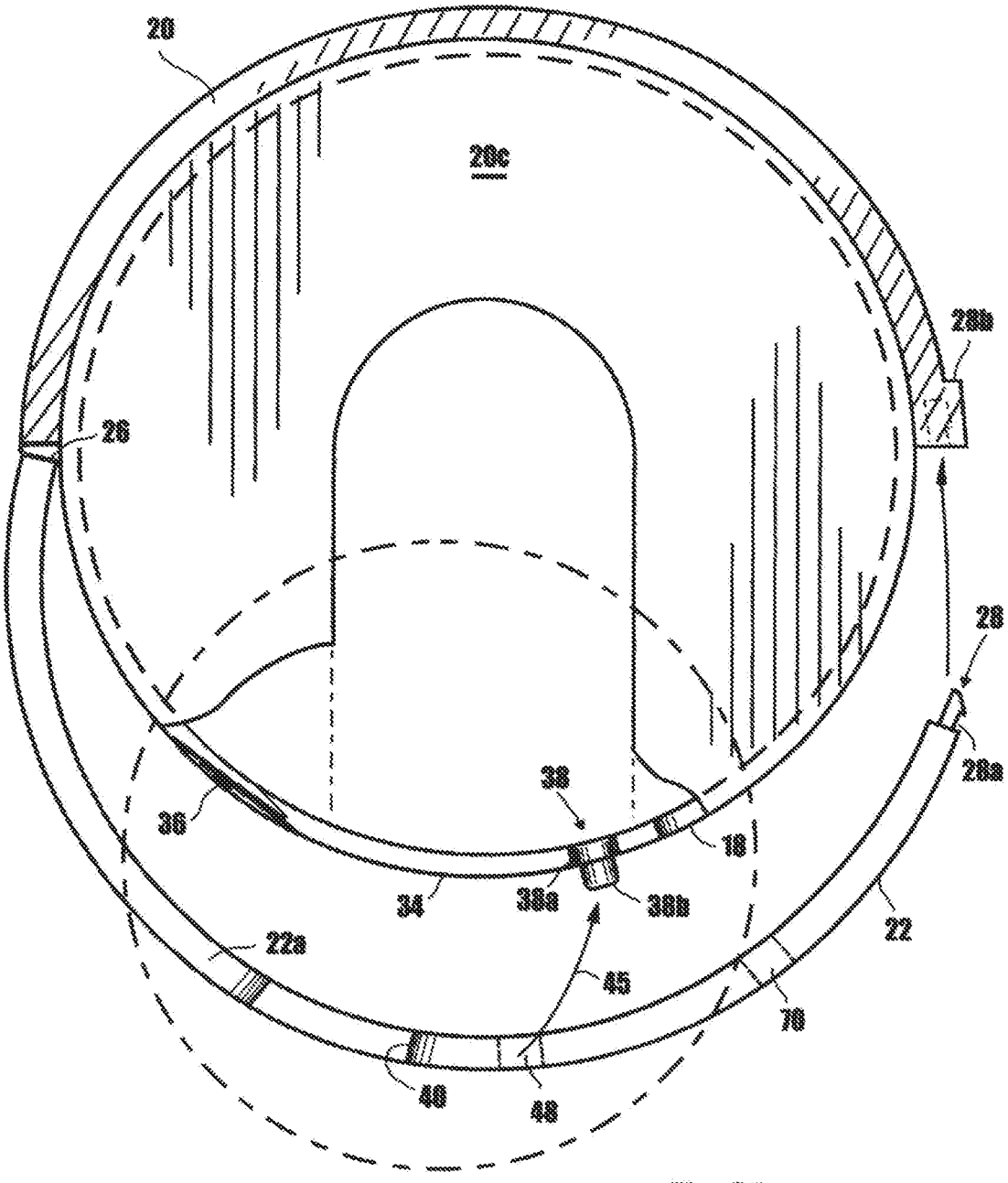
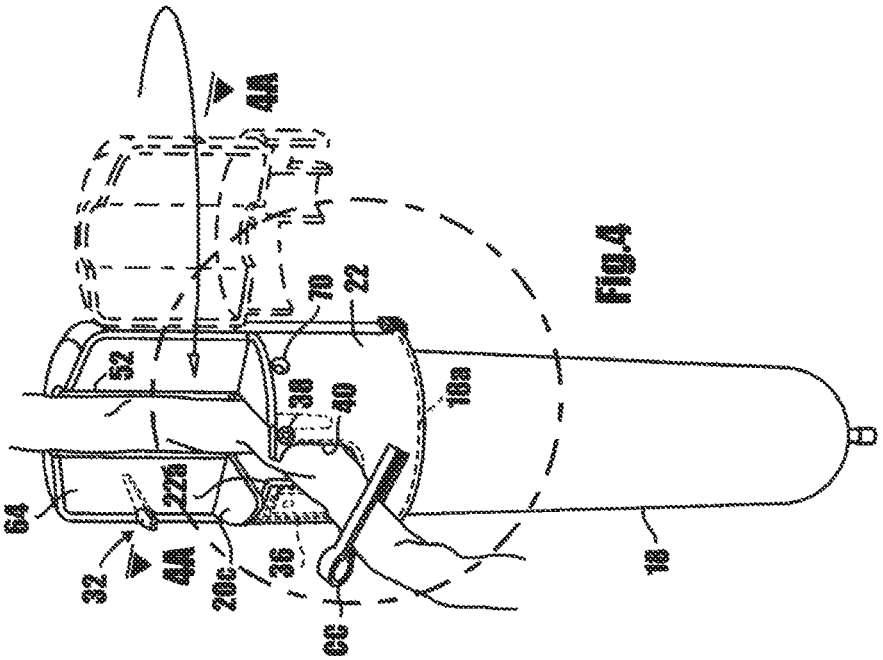


Fig 2A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70
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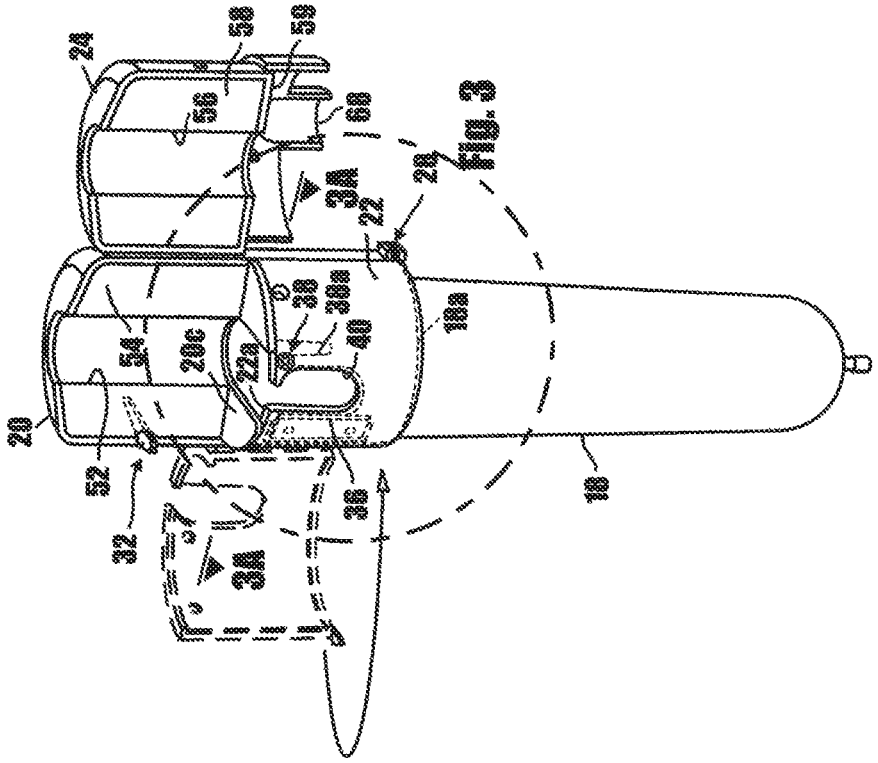
Fig.4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20c
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Fig. 3

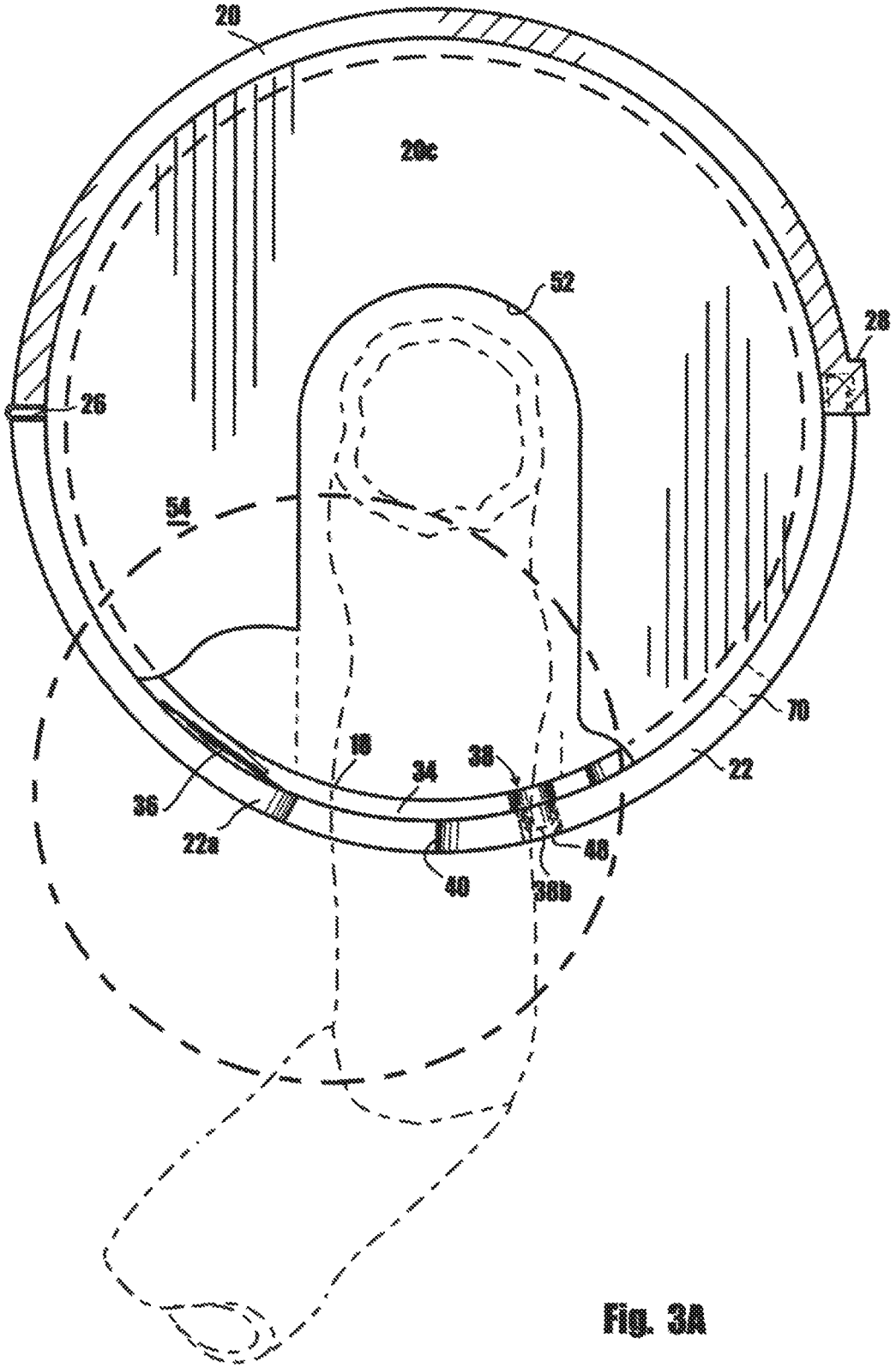

Fig. 3A

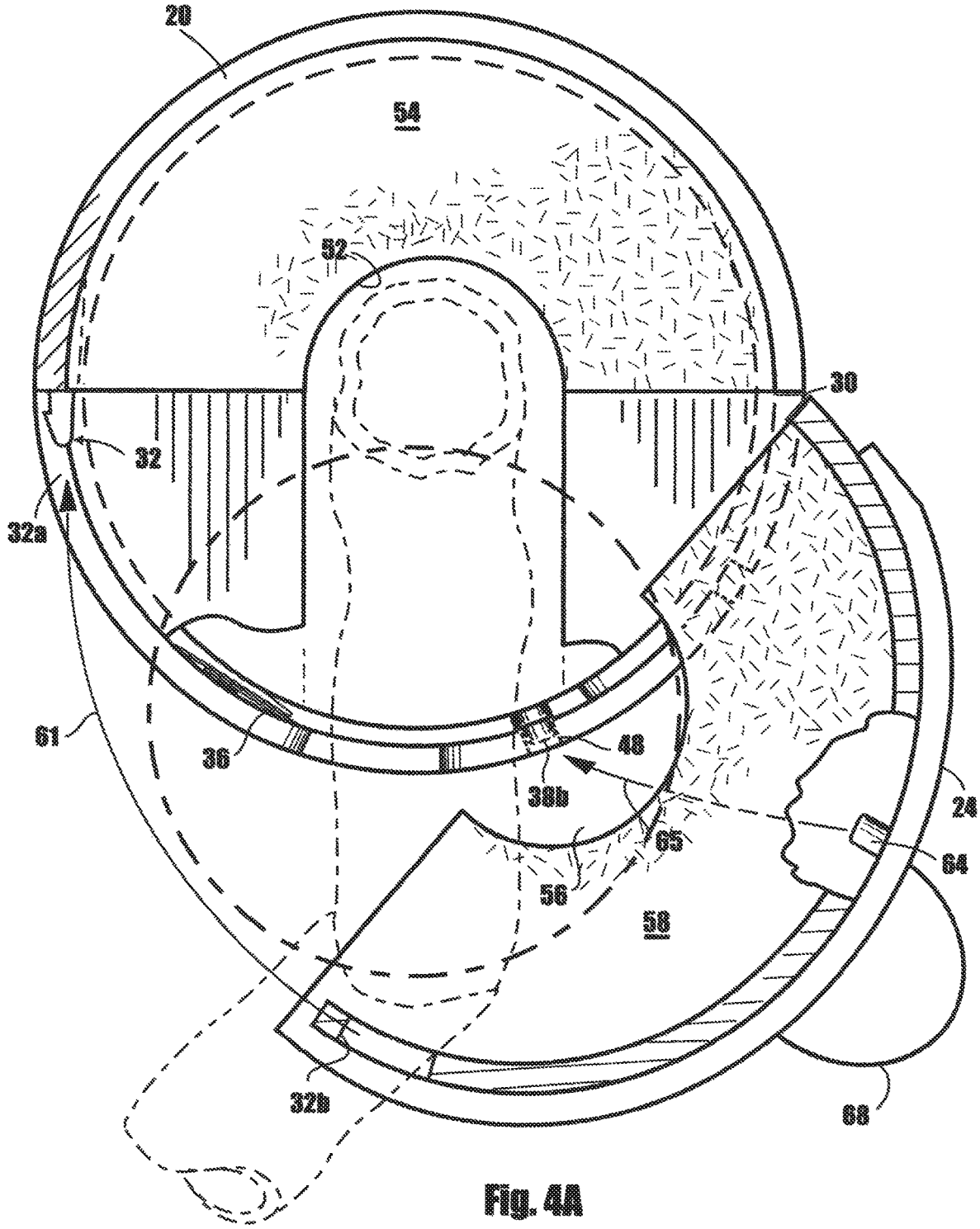

Fig. 4A

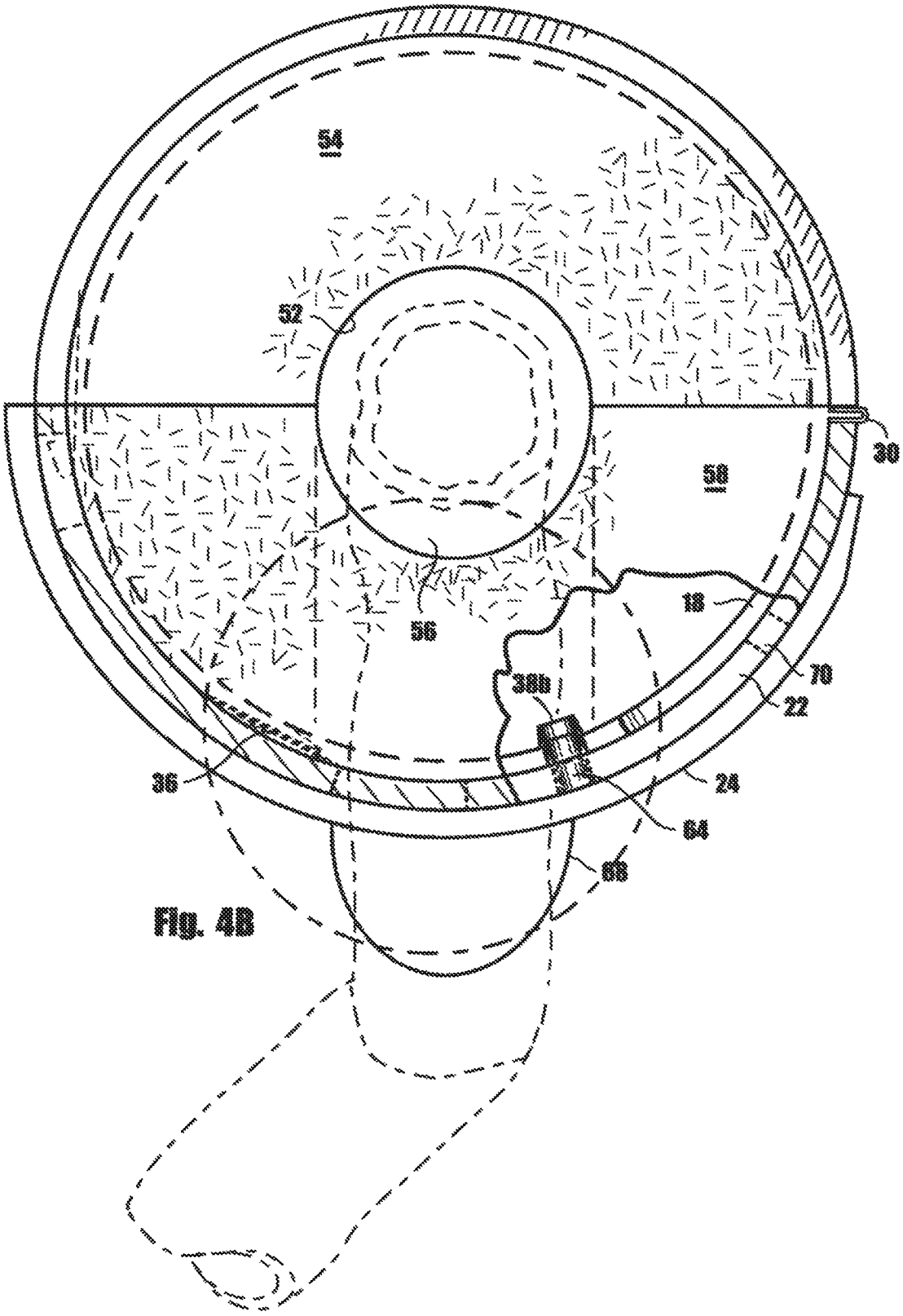

Fig. 4B

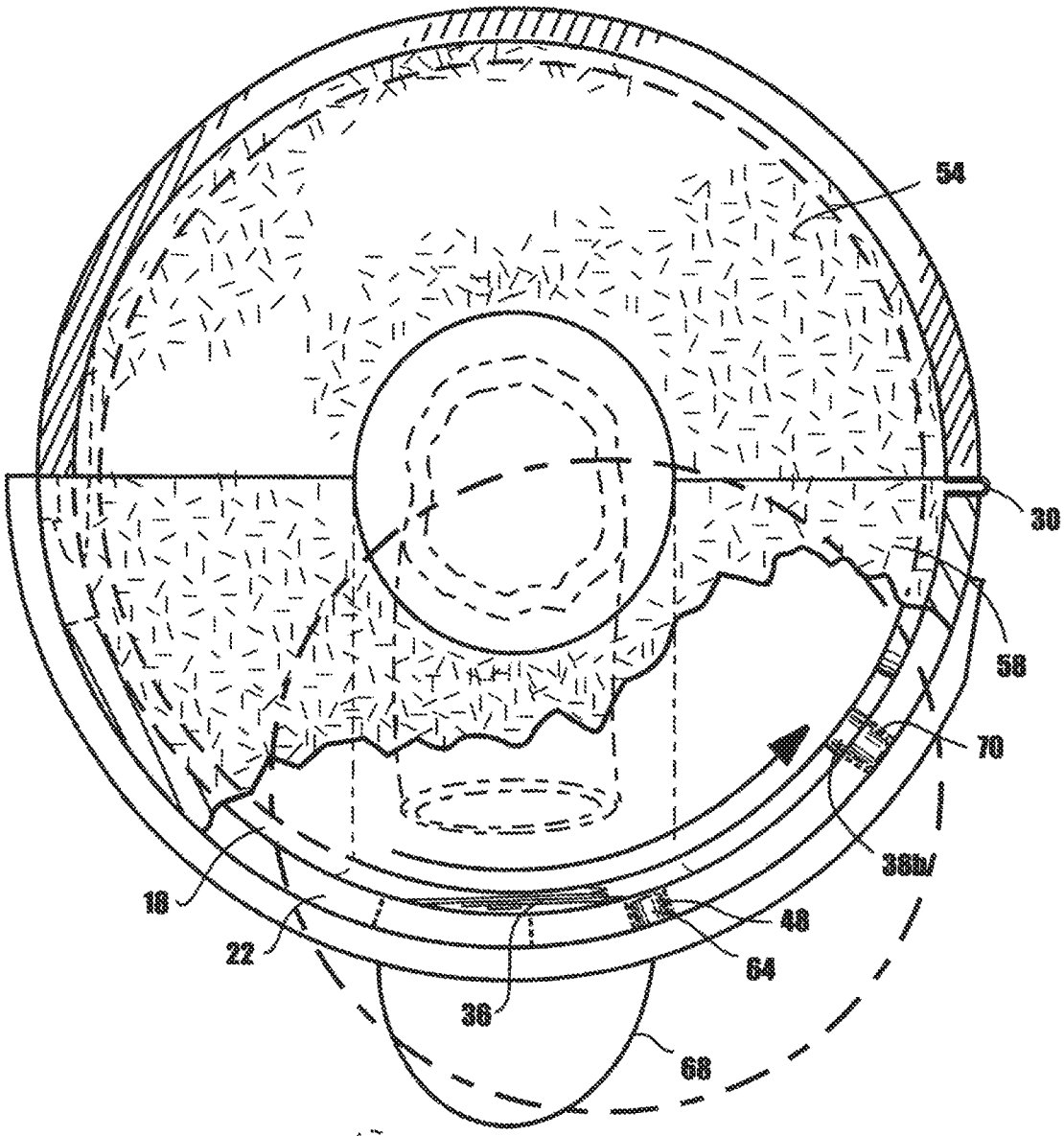

Fig. 4C

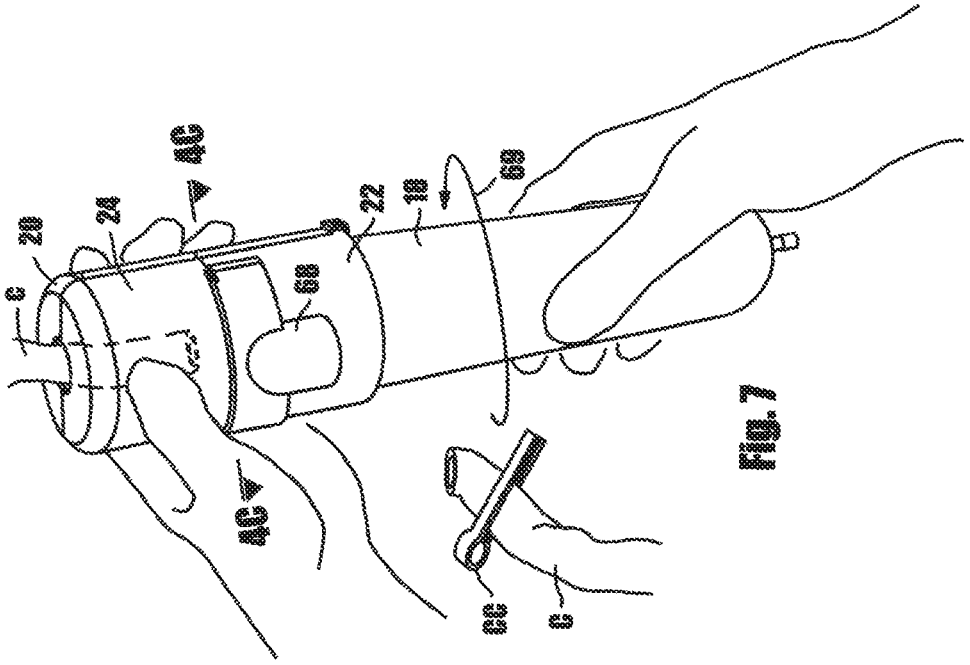

Fig. 7

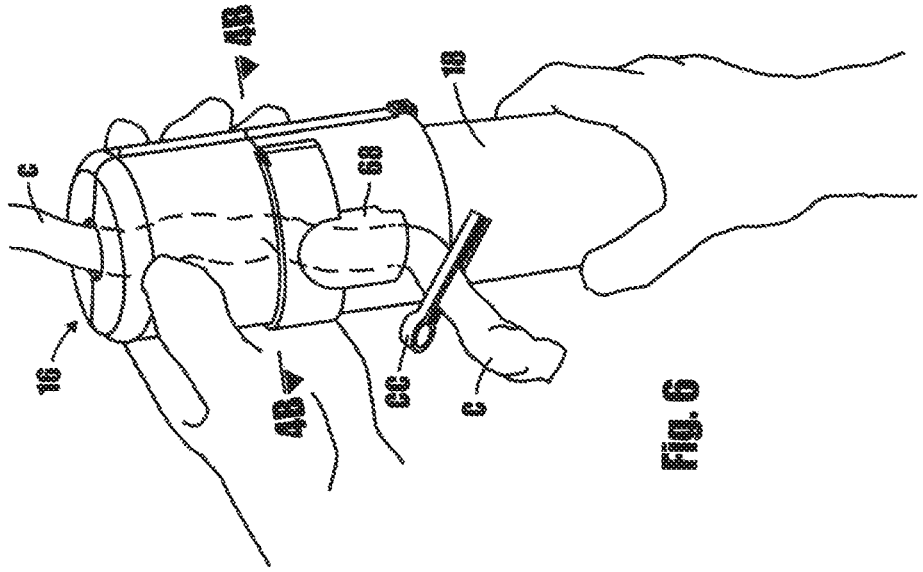

Fig. 6

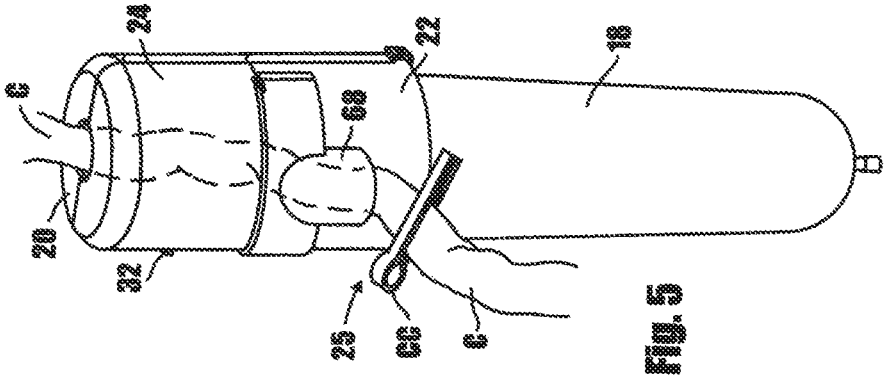

Fig. 5

CORD COLLECTION CLAMP

CROSS-REFERENCE TO RELATED APPLICATIONS

Not applicable

STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT

Not applicable

INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC

Not applicable

TECHNICAL FIELD

The present disclosure relates generally to blood collection devices. More particularly, the present disclosure concerns an apparatus and method for collecting blood from an umbilical cord.

INTRODUCTION

A sample of blood taken from a newborn baby's umbilical cord is a rich source of hematopoietic stem cells. Accordingly, cord blood has been used to treat a wide variety of diseases of the blood and immune system. Typically, cord blood is collected from the umbilical cord vein attached to the placenta after the umbilical cord has been detached from the newborn baby. Methods and devices for collection of cord blood are thus of interest.

SUMMARY

By way of brief summary, the present disclosure provides a novel cord collection clamp for collecting blood from an umbilical cord in an aseptic environment that includes an umbilical cord retainer assembly and a blood collection assembly that is rotatably connected to the cord retainer assembly. The cord retainer assembly includes a channel through which the umbilical cord passes and is provided with an outlet that communicates with the collection chamber of the blood collection assembly. The blood collection assembly is rotatably connected to the retainer assembly and uniquely includes a cord cutting blade that is strategically positioned to move from a first position to a second cord cutting position upon rotation of the collection assembly relative to said retainer assembly, thereby cutting the umbilical cord. The present disclosure also provides methods of collecting cord blood, as well as collecting a sample of the umbilical cord, using a device as described herein.

With the foregoing and mind, the present disclosure provides, in one embodiment, a cord collection clamp of the aforementioned character in which, during the umbilical cord cutting operation, the retainer assembly surrounds the umbilical cord and provides a biological seal.

In a further embodiment, the present disclosure provides a cord collection clamp of the class described which is safer to operate than the prior cord cutting devices because the cord cutting blade of the apparatus is better separated from the operator making careless handling less likely to expose a cutting surface to the operator.

In a further embodiment the present disclosure provides a cord collection clamp of the character described in which the retainer assembly includes a first segment overlaying a portion of the blood collection assembly, a second segment hingeably interconnected to the first segment and movable from a first position to a second position overlaying a portion of the blood collection assembly and a third segment hingeably interconnected to the second segment and movable from a first position to a second position overlaying a portion of said first segment and overlaying a portion of the blood collection assembly.

In a further embodiment, the present disclosure provides a cord collection clamp of the type described in the preceding paragraph in which movement of the second segment of the retainer assembly into the second position functions to safely cover the cutting blade of the blood collection assembly in a manner to prevent accidental cutting of the user and further functions to lockably engage the blood collection assembly in a manner to prevent rotation of the assembly relative to the retainer assembly in a manner to expose the operator to the cord cutting blade.

In a further embodiment, the present disclosure provides a cord collection clamp of the class described in the preceding paragraphs in which the blood collection assembly is provided with a locking member that is engaged by the second segment of the retainer assembly in a manner to block rotation of the blood collection assembly relative to the retainer assembly.

In a further embodiment, the present disclosure provides a cord collection clamp as described in the preceding paragraph in which upon movement of the third segment of the retainer assembly into the second position, the third segment functions to act upon the locking member of the blood collection assembly in a manner to move the locking member out of engagement with the second segment of the retainer assembly so as to permit rotation of the blood collection assembly relative to the retainer assembly thereby permitting safe cutting of the umbilical cord.

In a further embodiment, the present disclosure provides a cord collection clamp as described in the preceding paragraph in which continued rotation of the blood collection assembly relative to the retainer assembly will move the locking member into engagement with an aperture provided in the second segment of the retainer assembly so as to thereby block further rotation of the blood collection assembly relative to the retainer assembly thereby disabling the device.

In a further embodiment, the present disclosure provides a cord collection clamp as described in the preceding paragraph in which, upon cutting of the umbilical cord, blood from the umbilical cord will flow freely by force of gravity into the collection chamber of the blood collection assembly.

In a further embodiment, the present disclosure provides a cord collection clamp of the character described in the preceding paragraphs in which the blood collection chamber of the blood collection assembly is substantially closed to the external environment so that the blood from the umbilical cord is collected in a substantially aseptic environment.

In a further embodiment, the present disclosure provides a cord collection clamp of the character described in the preceding paragraphs that is ergonomically superior to the prior cord cutting devices and one that is easier and less expensive to produce than the prior cord cutting devices.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is an exploded, front elevational view of one form of the cord collection clamp of the present disclosure.

FIG. **2** is a front elevational view similar to FIG. **1**, but showing the collection assembly, or lower portion of the cord collection clamp interconnected with the central, or first segment of the retainer assembly of the cord collection clamp.

FIG. **2**A is a cross-sectional view of the first segment of the retainer assembly taken along lines **2**A-**2**A of FIG. **2** and showing the second segment of the retainer assembly rotated toward a closed position and further illustrating one form of the locking mechanism of the present disclosure for interlocking the second segment with the first segment.

FIG. **3** is a front elevational view similar to FIG. **2**, but showing the second segment of the retainer assembly of the cord collection clamp mated with the first segment of the retainer assembly.

FIG. **3**A is a cross-sectional view taken along lines **3**A-**3**A of FIG. **3** illustrating the second segment of the retainer assembly interlocked with the first segment of the retainer assembly and also interlocked with the collection assembly so as to prevent rotation of the collection assembly relative to the retainer assembly.

FIG. **4** is a front elevational view similar to FIG. **3**, but showing the uncut umbilical cord entrained through the cord receiving channel of the retainer assembly of the device, showing the third segment of the retainer assembly of the cord collection clamp in dotted lines and illustrating the manner in which the third segment is rotated to mate with the first segment of the retainer assembly.

FIG. **4**A is a cross-sectional view taken along lines **4**A-**4**A of FIG. **4** illustrating the second segment of the retainer assembly interlocked with the first segment and showing the third segment of the retainer assembly moved toward a closed position.

FIG. **4**B is a cross-sectional view taken along lines **4**B-**4**B of FIG. **6** showing the third segment of the retainer assembly moved into a closed position wherein it functions to act upon the locking protuberance of the collection assembly to permit rotation of the collection assembly relative to the retainer assembly.

FIG. **4**C is a cross-sectional view taken along lines **4**C-**4**C of FIG. **7** illustrating the rotation of the collector assembly of the present disclosure relative to the retainer assembly in a manner to cleanly cut the umbilical cord and also showing the relocking of the collector assembly against rotation relative to the retainer assembly to thereby disable the device from opening.

FIG. **5** is a front elevational view similar to FIG. **4**, but showing the third segment of the retainer assembly mated with the first segment of the retainer assembly.

FIG. **6** is a diagrammatic view similar to FIG. **5** showing the manner in which the retainer assembly is gripped by the user and the manner in which the collection assembly is gripped by the user prior to rotation of the collection assembly.

FIG. **7** is a diagrammatic view similar to FIG. **6**, but illustrating the manner in which the collection assembly is rotated relative to the retainer assembly to sever the umbilical cord.

DETAILED DESCRIPTION

Referring to the drawings and particularly to FIGS. **1** and **2**, one form of the cord collection clamp of the present disclosure for collecting blood from an umbilical cord is there shown and generally designated by the numeral **14**. The device here comprises two inter-connectable assemblies, namely an upper, or umbilical cord retainer assembly **16** and a lower, or blood collection assembly **18** that is rotatably connected to the umbilical cord retainer assembly.

The retainer assembly **16** uniquely comprises three hingeably interconnected segments, namely, a first, or central segment **20**, a second segment **22** and a third segment **24**. In a manner presently to be described, segments **20**, **22** and **24** cooperate to form the device housing **25** (FIG. **5**). As best seen by referring to FIG. **1** of the drawings, the first segment **20** has an upper portion **20***a*, a lower portion **20***b* and includes an intermediate partition wall **20***c* that divides the upper and lower portions. As depicted in FIG. **2** of the drawings, in using the device of the present disclosure, the upper portion **18***a* of the collection assembly seats within the lower portion **20***b* of first segment **20**.

As illustrated in FIG. **1**, second segment **22** of the retaining assembly is connected to first segment **20** by a living hinge **26** and, in a manner presently to be described, is movable from a first position shown in FIG. **2** of the drawings to a second position shown in FIG. **3** wherein it overlays the upper portion **18***a* of the collection assembly **18** and interlocks with first segment **20** by means of an interlocking mechanism **28** of conventional design the character of which is illustrated in FIG. **2**A of the drawings. As indicated in FIG. **3** interlocking mechanism **28** functions to interlock together first and second segments **20** and **22** when second segment **22** is in the second position.

Similarly, third segment **24** of the retaining assembly is connected to first segment **20** by a living hinge **30** and, in a manner presently to be described, is movable from a first position shown in FIG. **3** of the drawings to a second position shown in FIG. **5** wherein it overlays a portion of first segment **20** and interlocks with the first segment by means of a conventional locking mechanism **32** the character of which is illustrated in FIG. **4**A of the drawings.

As best seen in FIG. **1**, collection assembly **18** includes a collar **18***b* that is disposed intermediate upper portion **18***a* and lower catch reservoir portion **18***c*. The upper portion **18***a* of the collection assembly is provided with a generally U-shaped, umbilical cord receiving opening **34**. Mounted proximate opening **34** is the important umbilical cord cutting blade **36** of the present disclosure. The upper portion **18***a* of the collection assembly also includes a locking assembly **38**, which in a manner presently be described, functions to prevent accidental rotation of the collection assembly **18** relative to the retainer assembly **16**.

It is to be noted that upon closing second segment **22**, a generally U-shaped opening **40** formed in second segment **22** aligns with opening **34** formed in the collection assembly to permit passage of the umbilical cord. It is also important to note that upon closing second segment **22**, the cutting edge of cutting blade **36** is covered by the blade covering protective portion **22***a* of second segment **22** (see FIG. **4**). This important blade covering protective portion of the second segment, which is disposed proximate opening **40**, functions to effectively protect the operator from being accidentally cut by the blade during the positioning of the umbilical cord within the cord collection clamp (see also FIGS. **2**A and **3**A).

As illustrated in FIG. **1** of the drawings, center segment **20** of the retainer assembly **16** is provided with an inwardly extending shoulder **42**. Similarly, second segment **22** is provided with an inwardly extending shoulder **44** that mates with shoulder **42** when the second segment is moved into the closed position shown in FIG. **3** of the drawings. When the collection assembly **18** is mated with the retaining assembly in the manner shown in FIG. **2** of the drawings and when the second segment **22** is in the closed position, collar **18***b* the

of the collection assembly engages shoulders **42** and **44** and functions as a removal preventing assembly that prevents removal of the collection assembly from the retainer assembly. Additionally, in a manner next to be discussed and as illustrated in FIGS. **2**A and **3**A of the drawings, when the second segment **22** is moved into the closed position, collection assembly **18** will be locked against rotation relative to the retainer assembly **16**. This anti-rotation locking feature is accomplished by the previously identified locking assembly **38** which comprises a yieldably deformable locking finger **38***a* and a locking protuberance **38***b* that is formed proximate the extremity of the locking finger. As the second segment moves toward the closed position and as indicated by the arrow **45** in FIG. **2**A, locking protuberance **38***b* will be received within a locking protuberance receiving aperture **48** formed in the second segment. With the locking protuberance positioned within locking protuberance receiving aperture **48** in the manner shown in FIG. **3**A, the collection assembly **18** will be locked against rotation relative to the retainer assembly. Additionally, second segment **22** will be interlocked with segment **20** as the male portion **28***a* of interlocking mechanism **28** seats within female portion **28***b*.

With the cord collection clamp in the configuration illustrated in FIGS. **3** and **3**A, wherein the collector assembly **18** is locked against removal from the retainer assembly, wherein a portion of the second segment **22** protectively covers the cutting blade **36** and wherein the collector assembly **18** is locked against rotation relative to the retainer assembly, the umbilical cord (shown by the dotted lines in FIG. **3**A) can safely be positioned within the device in preparation of the cord cutting operation. With the conventional cord clamp CC in position so as to stop umbilical cord blood flow, the umbilical cord can be entrained through the online openings **34** and **40** in the manner illustrated in FIG. **4**. As the umbilical cord is so positioned, the cord will be seated within a channel **52** that is formed within a foam insert **54** that is mounted in the upper portion of first segment **20**. This done, the third segment **24** of the retainer assembly is moved from the position shown in the dotted lines in FIG. **4** into the closed position shown in FIG. **5**. With the third segment in the closed position, the umbilical cord is closely received within a channel **56** that is formed within a foam insert **58** that is mounted in the upper portion of third segment **24**. As illustrated in the drawings, foam insert **54** is supported within first segment **20** by the previously identified, inwardly extending wall **20***c*, while foam insert **58** is supported within third segment **24** by an intermediate, inwardly extending wall **59**. It is to be appreciated that with the construction thus described, the generally U-shaped cord receiving openings **34** and **40** formed in the collection assembly and in the cord retaining assembly respectfully, cooperate with channels **52** and **56** to form the umbilical cord retaining channel of the present disclosure which functions to support the umbilical cord during the cutting operation. However, in this regard, it is to be appreciated that the umbilical cord cutting operation cannot be accomplished until the yieldably deformable locking finger of the locking assembly **38** is acted upon by the release assembly of the present disclosure in a manner to permit rotation of the collection assembly relative to the cord retaining assembly. It is to be appreciated that movement of the third segment of the retainer assembly into the closed position shown in FIG. **5** not only clamps the umbilical cord in position, but also actuates the release assembly of the present disclosure in a manner next to be described. More particularly, as illustrated in FIGS. **4**A and **4**B of the drawings, as the third segment **24** moves into the closed position as indicated by the arrow **61** in FIG. **4**A, a release protuberance **64** provided on the inner wall of third segment, which forms a part of the release assembly of the present disclosure, moves toward protuberance **38***b* of assembly **38** in the direction of the arrow **65**. When the third segment **24** reaches the closed position shown in FIG. **4**B, the yieldably deformable locking finger along with protuberance **38***b* will have been moved inwardly by protuberance **64** and clear of aperture **48** formed in second segment **22** so as to no longer block rotation of the collection assembly. Additionally, third segment **24** will be interlocked with segment **20** as the locking tab **32***a* of interlocking mechanism **32** seats within tab receiving portion **32***b*. With the third segment **24** in the closed position, a protective sleeve **68** formed on third segment **24** covers the generally U-shaped opening **40** that forms a part of the umbilical cord channel and thereby functions to further protect the operator from accidental cutting by the cutting blade.

As illustrated in FIGS. **6** and **7** of the drawings, in accomplishing the severing operation, the retainer assembly is gripped with one hand of the user and the collection assembly is gripped by the other hand so that the collection assembly can be rotated in the manner indicated by the arrow **69** of FIG. **7**. As the collection assembly is rotated, the cutting blade will traverse the portion of the cord retaining channel defined by the cord receiving openings **34** and **40** thereby severing the umbilical cord. More particularly, as illustrated in FIGS. **4**B and **4**C, as the collection assembly is rotated, the cutting blade **36** will traverse the cord receiving opening **34** in said second segment of the retainer assembly thereby cleanly severing the umbilical cord in the manner shown in FIG. **4**C.

Referring particularly to FIG. **4**C of the drawings, it is to be noted that as the collection assembly **18** is rotated in the direction of the arrow of FIG. **4**C, the outwardly extending protuberance **38***b* formed on the deformable locking finger **38***a* will move into alignment with a disabling aperture **70**, which forms a part of the disabling assembly of the present disclosure, and will be lockably received there within thereby disabling the cord collection clamp and preventing further rotation of the collection assembly relative to the retaining assembly.

After the umbilical cord is severed, blood will flow from the cord via gravity into the blood collection region **18***c* of the collection assembly. Since the blood collection assembly is at this point substantially closed to the external environment, the blood is therefore collected in a substantially aseptic environment. In practice, the lower portion of the blood collection assembly acts as a funnel to funnel the blood toward an outlet port **18***p* to which an external collection bag (not shown) can be interconnected.

Having now described the present disclosure in detail in accordance with the requirements of the patent statutes, those skilled in this art will have no difficulty in making changes and modifications in the individual parts or their relative assembly in order to meet specific requirements or conditions. Such changes and modifications may be made without departing from the scope and spirit of the present disclosure as set forth in the following claims.

I claim:

1. A cord collection clamp for collecting blood from an umbilical cord comprising:

(a) a retainer assembly comprising a first segment, a second segment hingeably connected to said first segment, said second segment having a cord receiving opening and being movable from a first position to a second position overlaying a portion of the first seg-

ment, and a third segment hingeably connected to said first segment and movable from a first position to a second position overlaying a portion of (i) said first segment, (ii) said second segment and (iii) a blood collection assembly; and

(b) the blood collection assembly rotatably connected to said retainer assembly, said blood collection assembly having a cord receiving opening and a cord cutting blade constructed and arranged to traverse said cord receiving opening in said second segment of said retainer assembly upon rotation of said collection assembly relative to said retainer assembly,

wherein the third segment includes a protective sleeve constructed and arranged to cover said cord receiving opening in said second segment of said retainer assembly when said third segment is in said second position and said second segment is in said second position.

2. The cord collection clamp as defined in claim **1** in which said second segment of said retainer assembly further includes a protective covering portion arranged to cover said cord cutting blade when said second segment is in said second position.

3. The cord collection clamp as defined in claim **1** in which said second segment further includes a locking protuberance for blocking rotation of said blood collection assembly relative to said retainer assembly when said segment is in said second position.

4. The cord collection clamp as defined in claim **3** in which said third segment of said retaining assembly includes a release protuberance constructed and arranged to act upon said locking protuberance of said blood collection assembly to permit rotation of said blood collection assembly relative to said retainer assembly when said third segment is in said second position.

5. The cord collection clamp as defined in claim **4** in which said second segment of said retaining assembly includes a disabling aperture arranged to receive said locking protuberance of said collection assembly upon rotation of said blood collection assembly relative to said retainer assembly to block rotation of said blood collection assembly.

6. A method of collecting cord blood, the method comprising:

positioning an umbilical cord in the cord receiving opening of the retainer assembly of the cord collection clamp of claim **1**;

rotating the retainer assembly relative to the blood collection assembly thereby clamping the umbilical cord into position and actuating the cutting blade to cut the umbilical cord.

7. A cord collection clamp for collecting blood from an umbilical cord comprising:

(a) a retainer assembly comprising:

(i) a first segment;

(ii) a second segment hingeably connected to said first segment, said second segment having a cord receiving opening and being movable from a first position to a second position; and

(iii) a third segment hingeably connected to said first segment and movable from a first position to a second position overlaying a portion of said first segment and overlaying a portion of a blood collection assembly; and

(b) the blood collection assembly rotatably connected to said retainer assembly, said blood collection assembly having a cord receiving opening and a cord cutting blade constructed and arranged to traverse said cord receiving opening in said second segment of said retainer assembly upon rotation of said collection assembly relative to said retainer assembly,

which said second segment of said retainer assembly further includes a locking protuberance for blocking rotation of said blood collection assembly relative to said retainer assembly when said second segment is in said second position and in which said third segment of said retainer assembly includes a release protuberance constructed and arranged to act upon said locking protuberance of said collection assembly to permit rotation of said blood collection assembly relative to said retainer assembly when said third segment is in said second position.

8. The cord collection clamp as defined in claim **7** in which said second segment of said retainer assembly further includes a protective covering portion arranged to cover said cord cutting blade when said second segment is in said second position.

9. The cord collection clamp as defined in claim **7** in which said second segment of said retaining assembly includes a disabling aperture arranged to receive said locking protuberance upon rotation of said blood collection assembly relative to said retainer assembly to block rotation of said blood collection assembly.

10. A method of collecting cord blood, the method comprising:

positioning an umbilical cord in the cord receiving of the retainer assembly of the cord collection clamp of claim **7**;

rotating the retainer assembly relative to the collection assembly thereby clamping the umbilical cord into position and actuating the cutting blade to cut the umbilical cord.

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